

REMARKS

The above-identified Application has been carefully reviewed with the Office Action of January 19, 2011, the Examiner's comments, and the prior art references cited therein in mind. In response thereto, Applicant submits the foregoing amendments and the following arguments in support of patentability. Upon entry of the amendments in this response, claims 1, 3 – 8, 10, 11, 14 – 17, 19 – 24, 26, 27, 30 and 32 remain pending. In particular, Applicant amends claims 1, 10, 17, 26 and 30, and cancels claims 9 and 25 without prejudice, waiver, or disclaimer. Applicant cancels claims 9 and 25 merely to reduce the number of disputed issues and to facilitate early allowance and issuance of other claims in the present application. Applicant reserves the right to pursue the subject matter of these canceled claims in a continuing application, if Applicant so chooses, and does not intend to dedicate the canceled subject matter to the public. Reconsideration and allowance of the application and presently pending claims are respectfully requested.

I. Claim Amendments

The recitations of claim 9 have been added to amended claim 1 and the recitations of claim 25 have been added to amended claim 17.

The limitation "the stomach" in line 2 of claim 17 as been canceled to respond to the claim rejection under 35 U.S.C 112, second paragraph.

Claim 30 has been amended to recite limitations concerning the opening member and the locking means.

The aforementioned amendments are supported by the description, for example, page 17, lines 1 to 5: *"Advantageously, the cartridge 2 has a thread 12 with a first portion 19 sewn with a single-thread chain stitch, so as to form the locking means 4, and a second portion 14, 12A that remains free and forms the opener member 3 that can be actuated in traction."*

Therefore, no new matter is added.

Claim 30 has also been amended as suggested by the Examiner to indicate that the locking step further comprises locking the cartridge in substantially the shape of a sleeve to respond to the claim rejection under 35 U.S.C 112, second paragraph.

II. Rejections under 35 U.S.C 112, Second Paragraph

The Office Action indicates that claims 17 and 30 – 32 stand rejected under 35 U.S.C 112, second paragraph, for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. In this regard, Applicant has amended the claims as set forth above and respectfully asserts that the rejections have been rendered moot.

III. Rejections under 35 U.S.C 102

The Office Action indicates that claims 1-5, 9-10, 13-14, 17-21, 25-26, 29-31 and 33 have been rejected under 35 U.S.C. §102(b) as being anticipated by US 4,899,747 “Garren”. Applicant respectfully traverses.

A. Claim 1 is Allowable

In this regard, claim 1 (as amended) recites:

1. A kit for introducing a gastric implant into a stomach of a patient to treat obesity, the kit comprising:
 - an intragastric implant for implanting in the stomach in order to reduce its volume, said implant being expandable from a configuration for introduction into the stomach to a therapeutic configuration within the stomach; and
 - a cartridge for packaging said implant in the introduction configuration, said cartridge being provided with an opener member activatable by positive action enabling the cartridge to pass from a closed configuration in which the cartridge confines the implant in the implant's introduction configuration, to an open configuration in which the cartridge allows said implant to expand;
 - said cartridge also includes locking means functionally connected to the opener member and capable on its own, without requiring any external action on said locking means, of holding the cartridge in the closed configuration, said cartridge further comprises a sleeve provided

with at least one side opening formed along its length, said opening being closed by said locking means when said cartridge is in the closed configuration, and said opening being disengaged to allow the implant to expand when said cartridge is in the open configuration;

wherein the cartridge is provided with a thread having a first portion sewn as a single-thread chain stitch so as to form said locking means, and having a second portion that remains free and forms the opener member that can be actuated in traction.

(Emphasis added).

Applicant respectfully asserts that the cited art is legally deficient for anticipating claim 1. Specifically, the cited art does not teach or otherwise disclose at least the features emphasized above in claim 1. Notably, amended claim 1 integrates the recitation that the opener member is a first portion of a thread and the locking means is a single-thread chain stitch seam.

In contrast to the recitations above in claim 1, *Garren* discloses a thread as the opener member but the locking means is a zigzag fashion seam. See column 5, lines 4 to 7: “Next, a drawstring 38 is threaded through the loops 34 in ***zigzag fashion*** from the end of tube 20A upwardly and into the interior of the tube at the other end of the slit”. (Emphasis added). As such, Applicant respectfully requests that the rejection be withdrawn and that claim 1 and its dependent claims be placed in condition for allowance.

B. Claim 17 is Allowable

In this regard, claim 17 (as amended) recites:

17. A cartridge for introducing an intragastric implant in order to treat obesity, said implant being designed to be implanted in the stomach in order to reduce its volume and being expandable from a configuration for introduction into the stomach to a therapeutic configuration within the stomach, said cartridge being designed to package said intragastric implant in the introduction configuration and being provided with an opener member activatable by positive action enabling the cartridge to pass from a closed configuration in which the cartridge confines the intragastric implant in the intragastric implant's introduction configuration, to an open configuration in which the cartridge allows said intragastric implant to expand, said cartridge including locking means functionally connected to the opener member and capable on its own, without any external action on said opener means, of holding the cartridge in the closed configuration, said cartridge further comprises a sleeve provided with at least one side opening formed in its length, said side opening being closed by said locking means when said cartridge is in the closed

configuration, and said opening being disengaged to allow the surgical implant to expand when said cartridge is in the open configuration;
wherein the cartridge further includes a thread having a first portion sewn with a single-thread chain stitch so as to form the locking means, and having a second portion that remains free and forms the opener member that can be actuated in traction.

(Emphasis added).

Applicant respectfully asserts that the cited art is legally deficient for anticipating claim 17. Specifically, the cited art does not teach or otherwise disclose at least the features emphasized above in claim 17. Notably, amended claim 17 integrates the recitation that the opener member is a first portion of a thread and the locking means is a single-thread chain stitch seam.

In contrast to the recitations above in claim 17, *Garren* discloses a thread as the opener member but the locking means is a zigzag fashion seam. See column 5, lines 4 to 7: “Next, a drawstring 38 is threaded through the loops 34 in ***zigzag fashion*** from the end of tube 20A upwardly and into the interior of the tube at the other end of the slit”. (Emphasis added). As such, Applicant respectfully requests that the rejection be withdrawn and that claim 17 and its dependent claims be placed in condition for allowance.

C. Claim 30 is Allowable

In this regard, claim 30 (as amended) recites:

30. A method of manufacturing a kit for introducing an intragastric implant into a stomach of a patient to treat obesity, the method comprising the steps of:

supplying or making an intragastric implant for implanting in said stomach, said implant being expandable from a configuration for introduction in the stomach to a therapeutic configuration within the stomach;

supplying or making a cartridge for packaging said implant in the introduction configuration; and

providing said cartridge with a thread as an opener member activatable by positive action enabling the cartridge to pass from a closed configuration in which the cartridge is suitable for confining the implant in the intragastric implant's introduction configuration, to an open configuration in which the cartridge is suitable for allowing said surgical implant to expand; and

locking the cartridge in the closed configuration in

substantially the shape of a sleeve, the sleeve including at least one axial opening at one of the ends of said sleeve, in which the cartridge is provided with a single-thread chain stitch seam as a locking means capable on its own, without requiring any external action on said locking means, of holding the cartridge in the closed configuration, and in which said locking means is functionally connected to the opener member.

(Emphasis added).

Applicant respectfully asserts that the cited art is legally deficient for anticipating claim 30. Specifically, the cited art does not teach or otherwise disclose at least the features emphasized above in claim 30. Notably, amended claim 30 integrates the recitation that the opener member is a first portion of a thread and the locking means is a single-thread chain stitch seam.

In contrast to the recitations above in claim 30, *Garren* discloses a thread as the opener member but the locking means is a zigzag fashion seam. See column 5, lines 4 to 7: “Next, a drawstring 38 is threaded through the loops 34 in **zigzag fashion** from the end of tube 20A upwardly and into the interior of the tube at the other end of the slit”. (Emphasis added). As such, Applicant respectfully requests that the rejection be withdrawn and that claim 1 and its dependent claims be placed in condition for allowance.

IV. Rejections under 35 U.S.C 103

The Office Action indicates that claims 6, 11, 22 and 27 are rejected under 35 U.S.C. §103 as being obvious over *Garren* in view of US 6,315,792 (“*Armstrong*”). Additionally, the Office Action indicates that claims 7, 8, 23 and 24 are rejected under 35 U.S.C. §103 as being obvious over *Garren* in view of US 2004/0087976 (“*DeVries*”), and that claims 15 and 16 are rejected under 35 U.S.C. §103 as being obvious over *Garren* in view of US 3,211,152 (“*Stern*”). Further, the Office Action indicates that claim 32 is rejected under 35 U.S.C. §103 as being obvious over *Garren* in view of US 6,984,242 (“*Campbell*”). Applicant respectfully traverses.

With respect to non-obviousness, the closest prior art appears to be that of *Garren*.

However, in contrast to the teachings of *Garren*, the instant application involves a locking means as a single-thread chain stitch seam, as recited in the respective claims. Such a difference provides significant technical effects, such as a better resistance to lateral constraints and less risk of an accidental opening of the cartridge during the introduction and an easier unraveling of the sewing. Thus, *Garren* is inadequate for rendering the claims obvious. As set forth in detail below, the secondary references are inadequate for remedying the deficiencies of *Garren*.

To solve the technical problem, *Armstrong* teaches to coat integrally a small surgical implant like a stent with a knit-braid cartridge. However, *Armstrong* does not involve providing a cartridge for intragastric implants with a locking means to hold said cartridge in the closed configuration. So, the combination of *Garren* and *Armstrong* should be a knit-braid cartridge for intragastric implant that lacks a sleeve. For at least this reason, the combination of *Garren* and *Armstrong* is inadequate for rendering the claims unpatentable.

Furthermore, *Armstrong* deals with small surgical implants like stents or catheters. There is a big difference of size between these small surgical implants and intragastric implants like balloons, to such an extent that one of ordinary skill in the art would not be reasonably inclined to combine these teachings. For at least this additional reason, Applicant respectfully requests that the rejections be removed.

Much like *Armstrong*, *Campbell* deals with small surgical implants like stents or vascular implants. For the same reason as above, one of ordinary skill in the art would not be reasonably inclined to combine these teachings. For at least this reason, the combination of *Garren* and *Campbell* is inadequate for rendering the claims unpatentable.

Due to the differences between *Stern* (an Endotracheal tube with multiple balloons), *DeVries* (an Endoscopic device and method used for fastening multiple tissue layer) and the invention, one of ordinary skill in the art would not be reasonably inclined to combine these

teachings. For at least this reason, Applicant respectfully asserts that use of either in combination with *Garren* is improper and withdrawal of the rejections is respectfully requested.

Based on the above, amended independent claims 1, 17 and 30 are non-obvious in view of *the cited art*, either individually or in combination. Indeed, *Armstrong* doesn't disclose that the cartridge comprises a sleeve provided with at least one side opening formed in its length, said side opening being closed by said locking means when said cartridge is in the closed configuration.

V. Dependent Claims are Allowable

The pending dependent claims are believed to be allowable for at least the reason that these claims depend from their respective independent claims, the allowability of each of which is set forth above. See *In re Fine, Minnesota Mining and Mfg. Co. v. Chemque, Inc.*, 303 F.3d 1294, 1299 (Fed. Cir. 2002). Additionally, these claims recite other features that can serve as independent bases for patentability.

CONCLUSION

In light of the foregoing amendments and for at least the reasons set forth above, Applicants respectfully submit that all objections and/or rejections have been traversed, rendered moot, and/or accommodated, and that the pending claims are in condition for allowance. Favorable reconsideration and allowance of the present application and all pending claims are hereby courteously requested.

Any other statements in the Office Action that are not explicitly addressed herein are not intended to be admitted. In addition, any and all findings of inherency are traversed as not having been shown to be necessarily present. Furthermore, any and all findings of well-known art and Official Notice, or statements interpreted similarly, should not be considered well-known for the particular and specific reasons that the claimed combinations are too complex to support such conclusions and because the Office Action does not include specific findings predicated on sound technical and scientific reasoning to support such conclusions.

If, in the opinion of the Examiner, a telephonic conference would expedite the examination of this matter, the Examiner is invited to call the undersigned attorney at (770) 933-9500.

Respectfully submitted,



M. Paul Qualey, Jr., Reg. No. 43,024

**THOMAS, KAYDEN,
HORSTEMEYER & RISLEY, L.L.P.**
Suite 1500
600 Galleria Parkway N.W.
Atlanta, Georgia 30339
(770) 933-9500